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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,345	01/16/2002	William J. Roberts	1400-003	5831

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/01/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,345

Applicant(s)

ROBERTS, WILLIAM J.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,10-17,27,29 and 34-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-8 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 2,9,18,19,24-26,28,30-33 and 42-56 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,9 & 10. 6) ☐ Other:

First Office Action on the Merits

Election/Restrictions

1. Applicant's election with traverse of the species of 5 α -androst-1-ene-3,17 β -diol-3,17 β -di(ethylcarbonate) in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the grounds for the restriction are unclear and are not sufficiently explained. This is not found persuasive because it is stated in the previous Office Action that the requirement is for search purposes only and, thus, the examiner is unsure of what is unclear or not sufficiently explained. As stated in the previous Office Action, if applicant is traversing on the ground that the species are not patentably distinct, applicant is required to submit evidence or identify such evidence now of record showing the species to be obvious variants or to clearly admit on the record that this is the case (see paragraph #1).

The requirement is still deemed proper and is therefore made **FINAL**.

2. Based on applicant's election of species, claims 3, 5, 10-17, 27, 29 and 34-41 stand withdrawn from further consideration as being drawn to a nonelected species. Claims 1, 2, 4, 6-9, 18-26, 28, 30-33 and 42-56 will be examined to the extent they read on the elected species and 17 β -hydroxy-5 α -androst-1-ene-3-one-17 β -alkylcarbonate.

Claim Objections

3. Claims 2, 7, 26 and 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The instant claims recite the phrase "and mixtures thereof". However, the parent claim does not recite mixtures.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-26, 28, 30-33 and 42-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims creates confusion as to the claimed invention.

Claims 20-23 are drawn to compounds but recite a carrier. Is applicant claiming a compound or a composition? For the purpose of art rejection and because of the addition of a carrier, the examiner assumes applicant is claiming a composition.

Claims 24-26, 28, 30-33 and 42-56 recite "[a] method for increasing the concentration of a parent androgen in a subject in vivo..". The claims are indefinite because they do not point out with specificity to whom applicant is administering the compound. Is applicant administering to any subject or to those in need of an increase

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in concentration of said parent androgen? The present specification suggests administration is to subjects in need of increase concentrations of androgenic steroids. It is suggested that applicant insert the phrase "in need thereof" into claim 24.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4, 6-8, 20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohloff et al.

Ohloff et al. teach the compound 17 β -methoxycarbonyloxy-5 α -androst-1-en-3-one (see pages 203 and 205, compound VI). The compound and composition taught by the reference are encompassed by the instant claims.

Allowable Subject Matter

8. Claims 2, 9, 18 and 19 are objected to as being dependent upon a rejected base claim.

Note: The instant claims are allowable to the extent they read on the elected species and obvious variants thereof (i.e., 5 α -androst-1-ene-3,17diol-17 β -alkylcarbonates) and the compound of claim 9, i.e., 17 β -hydroxy-5 α -androst-1-ene-3-one-17-ethylcarbonate.

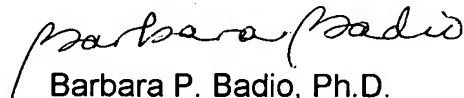
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Tel phone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
April 29, 2003